RD General Agenda Topics – June 28, 2021

Briefings for Michal

- PRIA/registration overview 2/23rd (complete)
- Dicamba 2/18th (complete)
- Sulfoxaflor 3/4th (complete)
- Pet incidents 3/31st (complete)
- FDA/EPA jurisdiction 4/12th (complete)
- SW2 revocation options 5/3rd (complete)
- Antibiotics 5/17th (complete)

New Active Ingredients (include original PRIA date)

- Tetraniliprole – completed!
- Broflanilide – completed!
- Picarbutrazox – completed!
- Fluxametamide – completed!
- Fluindapyr – completed!
- Trifludimoxazin – completed!
- Rekleml – PD being developed. PRIA date **7/19/21** (Original PRIA date 4/19/21) (IVB3). Partial ESA – coming to RD-IO soon
- Ipflufenoquin – PD being developed. PRIA date **7/30/31** (Original PRIA date 4/19/21) (FB). Working on ESA – out for comment
- L-Glufosinate Ammonium – Risk Assessment phase. PRIA date 10/12/2021 (FHB). ESA issue. Moving forward with incorporating ESA analysis.

Other Chemical Actions

- Dicamba
  - Bayer and BASF requesting feedback on pending pre-mixes
    - sent 75 day letters
  - **USDA conducting EIS** (instead of EA) on dicamba resistant corn; issued a 60-day public comment period 5/8th; citing EPA's cancellation order and 2020 decision. Discussed with OPMP. Comment period extended to 6/28. Coordinating with AO's OP and regions; OPP team recommends not sending substantive comments at this point
  - **24 (c)s –**
    - NC – denial 3/15th
    - TN – denial 4/9th
    - GA – denial 4/23rd
    - TX – Notice of intent to deny signed 6/15th; TX withdrew
    - GA – Tavium request; heads up from Syngenta
    - **MS – internal discussion with team today**
- **Antibiotics** – will need to brief the new team (FB)
    - Briefed Michal 5/17th; Received policy feedback on the antibiotic issue; Oxytet – cherry PRIA date of June – delay the action while we work on policy approach.
    - Settlement discussions on strep citrus use; which division is in charge of AART?

- **Inorganic Bromide** – R10 meeting with OPP; APHIS meeting with Michal – requesting increase in tolerance on alfalfa (Dan R)
- **Cyclaniliprole/flonicamid** –first residential use; public process; published proposal!
- **Seresto** – pet collar with high rate of incidents (death and neuro); press inquiries; 6a2 letter sent; updated desk statement to include factual information on FDA vs. EPA; received information from Elanco; team is developing a schedule
- **Aldicarb** – court vacated; RD will issue cancellation order working with OGC

Ex. 5 Deliberative Process (DP)

Other Actions - AA-Level/OD/High Visibility Items

- FDA/EPA jurisdiction – Michal follow up complete; team identified appropriate "model" MOUs and sent talking points; Ed is reaching out
- COVID-19 Activities – Sect 18s –
    - SW2 –

      Ex. 5 Deliberative Process (DP)
    - Grignard – reviews complete; working on authorization letters – meeting with Grignard to express concerns about promotional materials (NV, PA, TX, MD; amendment to TN and GA)
    - Kraton – completed!
    - Ionopure Air – risk issues
    - Acteev Facemasks
- OIG Audits

  Ex. 5 Deliberative Process (DP)
    - **PFAS** – RD working with Clark on submissions
        - Definition issue – working to bring Jeff D. up to speed
        - 6a2 notification? Nothing planned yet

- **Inerts** supply issue – phase 1 completed!; phase 2 – Revised response per comments
- **Inert** – Fragrance petition (Pat Quinn) – 2 petition responses scheduled for OGC review in June (Kerry); other petition responses will follow within existing resource constraints

- **CRP** (Child resistant Packaging) testing – industry has requested flexibilities in testing requirements due to COVID impacts; CPSC (whose regulations we use) have issued similar flexibilities. Team recommends issuing some but not all flexibilities. Next steps- COVID workgroup

- **IST** – Incident Screening Team

International

- Bi-monthly meeting with PMRA 5/11th – antibiotics, Seresto – complete; next meeting July
- PMRA – industry JR meeting 6/29th
- WPP meeting – 7/2nd

Business/process/technology

- ISB – FEP/21-day backlog:
  - backlog addressed by end of April; RD SWAT team addressing newer receipts
  - Working to complete RD SWAT actions
- eCSF/OPPEL – eCSF May 9th soft launch; OPPEL -TBD
- MRL – structured data for OPP and share with FDA; FDA is applying for internal grant – supports OPP digital transformation; OPP serving as reviewer

Speaking Engagements –

People/Personnel/Resources

Ex. 5 Deliberative Process (DP)

CA topics (Karen Morrison):

- Missing environmental hazard statements – RD BC's are generating a response